



**CENTER FOR
BIOSECURITY,
FOOD SAFETY,
& PUBLIC
HEALTH**

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December 23, 2003

Docket No. 03-080-1
Regulatory Analysis and Development
PPD, APHIS, Station 3C71
4700 River Road Unit 118
Riverdale, MD. 20737-1238

Dear Sir or Madam:

The comments relative to the proposed rule will not address the specifics of the policies described, nor for that matter, the thinking that went into the rationalization to defining a minimal-risk region including the extensive supporting documentation and references. This initiative is a generic summation of the entire proposal and comments will be limited to aspects of the proposed that could impact the rendering industry. As a respondent, I am also conscious that the burden of responsibility is for Canadian compliance with the requirements. Nonetheless, there are aspects of the proposal that need further scrutiny and consideration by the agency. Those are addressed for your evaluation.

OBJECTIVE OF THE PROPOSED RULE

The Center for Bio-security, Food Safety & Public Health (CBFSPH) references the proposed rule published in the Federal Register, Vol. 68, No. 213 November 4, 2003, to amend the regulations regarding the importation of animals and animal products to recognize a category of regions that present a minimal risk of introducing bovine spongiform encephalopathy (BSE) into the United States via live ruminants and ruminant products, with special applicability to Canada.

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SUPPLEMENTARY INFORMATION (Background, Definitions, Evaluations/Assessments of Risk)

The agency's supplementary information in the proposal including the descriptive epidemiological determinants used under the different sub-headings were state-of-the art for risk analysis, and served to reassure that designating Canada as a BSE minimal-risk region was a logical decision, validated and affirmed by comprehensive assessments of the known risks linked to BSE. This was further exemplified under the definition of bovine spongiform encephalopathy minimal-risk region, and the specific elements/factors used to evaluate Canada's likely conformance to the proposed risk categorization.

The proposed rule should be especially reassuring to those who espouse stringent controls to preclude the likelihood of transmission or amplification of BSE from entering the United States. The instituted controls in the proposal were science-based and conform to the existing known relative risks linked to BSE and its prevention. Unfortunately, while the likely opening of the border to Canadian cattle and specified meat products were heightened by the media, very few reports took the initiative to highlight the stringent preventive controls that were established in the proposed rule prior to the resumption of trade. In actuality, every conceivable factor was addressed, even the requirement to remove the intestines from imported cattle from Canada, destined to U.S. feedlots, in spite of the very limited risk. In essence, the requirements imposed on Canadian cattle and meat products were based on worst-case assumptions.

THE TALLOW PERSPECTIVE

While the agency should be fully commended on its BSE control parameters as defined in the proposed rule, the issue of tallow must be addressed using the same scientific principles of risk assessment. From the perspective of science, tallow

should never be considered a risk factor. As early as 1991, the World Health Organization (WHO) assembled consultants that determined tallow was safe, and not a risk to animal or human health.

Work done by Taylor et al. at the Animal Health Institute (AHI) in Edinburgh, Scotland, (about the only available reference on the subject) indicates that: (a) epidemiological studies failed to find any association between the occurrence of BSE and the consumption of tallow by cattle; and (b) in BSE-spiked rendering studies, no infectivity was detectable in crude, unfiltered tallow produced by a traditional rendering procedure.

Taylor et al. validated their research findings by injecting homogenates of spiked-BSE infected tallow intracerebrally (IC) into experimental mice and could not demonstrate the classical spongiform changes associated with a transmissible spongiform encephalopathy (TSE), even after a prolonged period of observation.

To be consistent, if the agency is using state-of-the art epidemiological principles to support its proposed rule, it should, therefore, not deviate from the known science of BSE transmission, nor should the agency accept any of the anecdotal inferences that tallow could have been fed to calves in "milk replacer" formulations in one or more of the Japanese BSE outbreaks. That analogy was both uncertain and circumstantial, and never linked to other cases of reported BSE incidents throughout the world.

Our government through official channels has debated the European Union (EU) on the safety of tallow for a decade, and it would now be inconsistent to "change tunes" without scientific validation that proves otherwise. This also applies to the inference that "the tallow is not derived from an animal that died otherwise than by slaughter." This is both premature and a form of disenfranchisement to the rendering industry globally.

In an objective analysis, while the general tenet of the proposed rule is commendable and amplifies an excellent evaluation of the existing minimal risk of a region (Canada, specifically) of introducing BSE into the United States, the proposal deviated from science in part, and indulged in its own "precautionary principles" of a product (tallow) that has not been shown to constitute any risk of transmitting BSE.

COMMENTARY/RECOMMENDATIONS

CBFSPH is supportive of the logical and commonsensical approach of the elements of the proposed rule and the thematic minimal risk categorization relative to Canada. The Center further suggests that for the sake of consistency, uniformity, and a science-based affirmation, that the agency seriously reconsiders exempting the limits placed on tallow in its entirety, including the reference "not derived from an animal that died otherwise than by slaughter."

This proposed rule not only defines with supporting rationale a category of regions that present a minimal BSE risk, but, introduces a new and progressive thinking of risk categorization that could hopefully have a future influence on global policy initiatives. It is basically sound and sets the stage for an alternative option to traditional BSE policy (ies).

On the subject of disposal of dead animals and parts that permits a "manner approved by the Administrator," CBFSPH strongly recommends that controls be instituted to involve rendering as the most logical option to insure bio-security. The rendering industry pending the agency's other considerations would doubtless like to provide concepts of the role that it can play in the process. They should be given an opportunity to present their concerns and recommendations to representatives of the Administrator. Their experience could prove invaluable to the agency and serve as an additional resource in the prevention of BSE.

SUMMARY

In closing, it is impossible not to reflect on the fact that the history of BSE is a prime example of how to deal with uncertainty and how control measures must be based on current knowledge and validated science. The “genesis” of the disease over the years has also shown the value and appreciation of risk analysis in guiding an objective and rational approach to animal disease control, both within countries, and on the global scene. This assists the “benchmarks” for managing the disease itself, while at the same time taking care of the varied dimensions of trade. These are significant factors in the prevention of major disruptions that could have serious negative consequences on livestock agriculture (particularly the cattle industry), and, to a lesser degree, other aspects of sustainable agriculture, including allied sectors, and the rendering industry.

The proposed rule made a concerted effort to amplify risk analysis to new applicable levels and the agency should be commended for its approach. CBFSPH offers the aforementioned suggestions as an option to improve the proposed rule and will work with the agency in promoting the objectives. BSE policies of the future must be put in perspective, and the agency has succeeded by this refreshing and novel approach. This is especially relevant since concerns have surfaced again that BSE may be associated with a genetic mutation based on cases that continue to be reported after the “feed ban.” One Cambridge University scientist (Malcolm Ferguson-Smith) recently conceded that the hypothesis that “infected animal feed is still reaching farms becomes increasingly untenable as time goes by.” Thus, while feed could likely play a role in the pathogenesis of prion diseases, based on the original hypothesis of the United Kingdom epidemiologists, co-factors must be seriously considered in disease causation.

British scientists are particularly concerned about trends in prevalence. There have been 77 cases of BSE in British cattle born after August 1996, but of these 49 were reported in the past 12 months and eight in the past six weeks.

The atypical BSE cases reported recently in both Italy and Japan should be reason for a continuing determination of the cause of this disease. While this has no direct impact on the proposed rule, fully supported by CBFSPH, it does demonstrate the obvious complexity of all the transmissible spongiform encephalopathies (TSEs).

CBFSPH reiterates its commendation of the agency in objectively addressing the elements of risk, and makes a plea for consideration on the issues addressed that the Center does not think can be validated by science.

Sincerely,

A handwritten signature in cursive script, appearing to read "Don A. Franco".

Don A. Franco, DVM, MPH, DVPM
President, CBFSPH

Cc Bobby Acord, Administrator, APHIS